# JC03 Rec'd PCT/PTO 1 1 MAY 2005

Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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### ATTTORNEY'S DOCKET NUMBER TRANSMITTAL LETTER TO THE UNITED STATES 3121US0P DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/JP2003/014339 November 12, 2003 November 13, 2002 TITLE OF INVENTION SCREENING METHOD APPLICANT(S) FOR DO/EO/US Takanori MATSUO; Hiroko TSUGE; Masatoshi HAZAMA Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. V An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7 Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT

Article 36 (35 U.S.C. 371(c)(5)).

	Items	11 to 20 below concern document(s) or information included:
11.	V	An Information Disclosure Statement under 37 CFR 1.97 and 1.98. Cited References
12.	V	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.	V	A preliminary amendment.
14.		An Application Data Sheet under 37 CFR 1.76.
15.		A substitute specification.
16.		A power of attorney and/or change of address letter.
17.	$\overline{\mathbf{v}}$	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
18.		A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19.		A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20.	V	Return Postcard; Certificate of Express Mailing; PCT Request; Cover Page International Application; Forms PCT/IB/301, 304, 306, 308, Other items or information: 332; ISR

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO-1390 (Rev. 12-2004)
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U.S. APPLICANT	075344	PLICATION NO.	ATTORNEY'S DOCKET NUMBER						
		3121US0P							
21. The following fees are submitted:  a) Basic national fee									
		<del> </del>							
b) Examin	ation fee	\$							
c) Search f	ee	\$							
	TOTAL OF ABOVE CA	\$ 1,000.00							
TOTAL OF ABOVE CALCULATIONS = \$1000.00  Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.									
Total Sheets	Extra sheets	Number of each additional 50 or fracti thereof (round up to a whole numbe							
91 - 100 =	N/A /50 =	N/A		x \$250.00	\$ -0-				
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).									
CLAIMS	NUMBER FIL	_ED	NUMBER EXTRA	RATE	\$	<b>1</b>			
Total claims	33	- 20 =	13	x \$50.00	\$ 650.00				
Independent clai	ms 14	-3=	11	× \$200.00	\$ 2,200.00				
MULTIPLE DEP	ENDENT CLAIM(S) (if ap	plicable)	··	+ \$360.00	\$				
TOTAL OF ABOVE CALCULATIONS = \$ 3,850.00									
Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.									
,	SUBTOTAL = \$ 3,850.00								
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest									
claimed priority o	claimed priority date (37 CFR 1.492(f)). + TOTAL NATIONAL FEE = \$ 3,850.00								
	the enclosed assignment	\$ 40.00							
by an appropriate	e cover sheet (37 CFR 3.								
		Amount to be	T <sub>s</sub>						
		refunded:	<b>3</b>						
		charged:	\$ 3,890.00						
a. A check in the amount of \$ to cover the above fees is enclosed.									
b. Please charge my Deposit Account No. 500799 in the amount of \$ 3,890.00 to cover the above fees.  A duplicate copy of this sheet is enclosed.									
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 500799. A duplicate copy of this sheet is enclosed.									
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.									
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 OFR 1.137(a) or b)) must be filed and granted to restore the International Application to pending status.									
SEND ALL CORRESPONDENCE TO:									
Mark Chao, Ph.D., JD									
	naceuticals North America,								
475 Half Day I		Chao, Ph.D., JD							
	L 60069 USA								
(847)383-337	2 fax (847)383-3409	7,293							
		ON NUMBER ner No. 23,115							

FORM PTO-1390 (REV. 12-2004)

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# JC14 Resid PCT/PTO 11 MAY 2005

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

Based on PCT/JP2003/014339

Intl. Filing 12 NOVEMBER 2003

1<sup>st</sup> Inventor:

Takanori MATSUO

For:

Filed:

Screening Method

Atty. Dkt. No.

3121 US0P

Art Unit:

tba

Examiner: tba

Allowed:

Batch:

Paper No.:

## **CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10**

#### USPS EXPRESS MAIL LABEL. No. EV 524904335 US

DATE IN:

May 11, 2005

### Itemized Papers/Items:

- 1. This Postcard and Certificate of Express Mailing (2 pages)
- 2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
- 3. Specification total pages 91, including Claims 1-37 (pages 80-86, Abstract (1 page), Drawings (1 page), and Sequence Listing (3 pages)
- 4. PCT Request (5 pages)
- 5. Declaration and Power of Attorney (4 pages)
- 6. Copies of Forms PCT/IB/ 301,304, 306,308,332 (6 pages)
- 7. Copy of Cover Page International Application (WO 2004/044199) (1 page)
- 8. Copy of International Search Report (4 pages)
- 9. Preliminary Amendment (11 pages)
- 10. Information Disclosure Statement (1 page), Form PTO/SB/08A and PTO/SB/08B (2 pages), cited references (6)
- 11. Submission of Sequence Listing Requirements (1 page), CRF of Sequence Listing (3 pages), and IBM PC/AT format disk containing the CRF of the Sequence Listing.
- 12. Executed Assignment (2 pages) and Recordation Cover Sheet (1 page X 2)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP PCT P.O. BOX 1450

Commissioner for Patents Alexandria, VA 22313-1450

on this date, 5/11/05

Dated: 5/11/08

Gail I Winokur

Takeda Pharmaceuticals North America, Inc. Intellectual Property Department 475 Half Day Road Lincolnshire, IL 60069 USA